Customer No. 00270

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of	) Group Art Unit: 1632
James M. Wilson et al	) Examiner: R. Shukla
Appln No. 09/757,673	)
Filed: January 10, 2001	)
For: METHOD FOR RECOMBINANT ADENO-ASSOCIATED VIRUS-DIRECTED GENE THERAPY	)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION PURSUANT TO 37 CFR 1.132

Sir:

I, James M. Wilson, residing at 1350 N. Avignon Drive, Gladwyne, Pennsylvania 19035, do declare and state that:

1. I am a co-inventor of the above-identified patent application and I have reviewed the current Office Action, the pending claims, US Patent No. 5,858,351, Podsakoff et al ("Podsakoff") and Fisher et al, J. Virol., 79:520-532 (1996) ("Fisher").

2. I have also reviewed the Declaration of Dr. Guangping Gao and am familiar with the experiments performed under the direction of Dr. Gao in the laboratories of The University of Pennsylvania.

3. Podsakoff at column 18, lines 20-35, describes production of recombinant AAV (rAAV) virions in human 293 cells. 293 cells were transfected by standard calcium phosphate precipitation with rAAV, infected with human adenovirus

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serotype 2 (Ad2) and incubated as described. Cells were ultimately layered onto a cesium chloride gradient centrifugation, extracted from the gradient and heat inactivated. While heat treatment of the helper adenovirus can affect the infectivity of the adenovirus, heat treatment does not remove helper adenovirus or adenoviral protein contaminants. Helper adenovirus and adenoviral protein contaminants are immunogenic, regardless of heat treatment.

4. As described in the specification, it is advantageous to provide rAAV that has reduced contamination with helper adenovirus and adenovirus proteins. The results of the experiments described in the Declaration of Dr. Gao demonstrate that there is a reduction in helper adenovirus and adenovirus protein contaminants in rAAV preparations achieved by each subsequent round of cesium chloride gradient centrifugation.

5. Reduction of contamination with helper adenovirus and adenovirus proteins may be achieved by conventional means known by one of skill in the art at the time of the above-identified application and include, *e.g.*, fractionation methods, size exclusion columns; and other methods based on separation by size and density. These methods are capable of providing a rAAV at least as free of contamination with helper adenovirus and adenovirus proteins as that provided by the four rounds of cesium chloride gradient centrifugation exemplified in the application. Furthermore, methods to measure helper adenovirus and adenovirus protein contamination levels were known by one of skill in the art at the time of filing of the above-identified patent application and include, e.g., Western blot, ELISA, and PCR techniques.

6. As a person signing below, I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and

that such willful false statements may jeopardize the validity of the application or any patent issues thereon.

James M. Wilson

Date: 5-11-04

CURRICULUM VITAE

PERSONAL DATA:

Name:	James M. Wilson
Born:	May 29, 1955

EDUCATION:

Undergraduate:	B.A., Chemistry, Albion College, Albion, Michigan, 1973-1977
Graduate:	Ph.D., Biological Chemistry, University of Michigan Medical School, Ann Arbor, Michigan, 1977-1984
Professional:	M.D., University of Michigan Medical School, Ann Arbor, Michigan, 1977-1984

POSTGRADUATE TRAINING:

Internship:	Medical Services, Massachusetts General Hospital Boston, Massachusetts, 1984-1985
Residency:	Medical Services, Massachusetts General Hospital Boston, Massachusetts, 1985-1986
Research Fellowship:	Postdoctoral Fellow at the Whitehead Institute, Massachusetts Institute of Technology, 1986-1988

PAST ACADEMIC APPOINTMENTS:

Assistant Professor to Associate Professor,
Internal Medicine and Biological Chemistry
University of Michigan, 1988-1993

Assistant Investigator, Howard Hughes Medical Institute
University of Michigan, 1988-1993

Chief, Division of Molecular Medicine and Genetics
University of Michigan, 1991-1993

Chief, Division of Medical Genetics, Department of Medicine
University of Pennsylvania, 1993-2000

Professor and Chair, Department of Molecular and Cellular Engineering
University of Pennsylvania, 1993-2001

Director, Institute for Human Gene Therapy
University of Pennsylvania, 1993-2002

CURRENT ACADEMIC APPOINTMENTS:

Professor of Medicine
University of Pennsylvania, 1993-Present

John Herr Musser Professor of Research Medicine
University of Pennsylvania, 1993-Present

Professor, The Wistar Institute, 1993-Present

Head, Gene Therapy Program
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BOARDS AND CONSULTING POSITIONS:

1988-1990	Member, Scientific Advisory Board and Consultant Somatix, Inc., Cambridge, MA,
1991-1992	Member, Scientific Advisory Board, Targetech, Inc.
1993-2002	Member, Medical Advisory Council, Cystic Fibrosis Foundation
1994-1997	Member, Genomics Advisory Board, SmithKline Beecham Pharmaceuticals
1995-1999	Member, Advisory Council, National Center for Research Resources, National Institutes of Health
1995-2000	Consultant, Genovo, Inc.
1996-present	Trustee, The Franklin Institute Member, New Ventures Committee; Franklin Center Committee
1998-present	Member, External Advisory Committee, Therapeutics Development Centers Program, Cystic Fibrosis Foundation
1998-present	Chairman, Gene Therapy Task Force, Muscular Dystrophy Association
1998-present	Member, Executive Committee, Combined Degree Physician Scholar Program, University of Pennsylvania
1998-present	Member, External Scientific Advisory Committee, Pittsburgh Human Gene Therapy Center
1999-present	Trustee, Albion College
1999-present	Member, Advisory Committee for the Career Awards in the Biomedical Sciences Program, Burroughs Welcome Fund
1999-2000	Member, Drug Development Advisory Committee, Cystic Fibrosis Foundation
1999-present	Member, Scientific Task Force, Juvenile Diabetes Research Foundation
2001-present	Member, Board of Advisors, The Stop ALD Foundation

2001-present	Member, NIDDK Medical Student Research Training Program University of Pennsylvania, Advisory Committee
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EDITORIAL POSITIONS

1991-1995	Human Gene Therapy, Editorial Board
1993-present	Somatic Cell and Molecular Genetics, Editorial Board
1993-present	Gene Therapy, Editorial Board
1995-2003	Human Gene Therapy, Associate Editor
1995-2004	Journal of Virology, Editorial Board
1996-present	Circulation, Editorial Board
1997-present	Molecular Medicine, Editorial Board
1997-present	DNA and Cell Biology, Editorial Board
1998-present	Journal of Clinical Investigation, Editorial Board
1998-present	Journal of Genetic Medicine, Editorial Board
1999-2003	Molecular Therapy, Associate Editor
1999-present	Regenerative Medicine, Associate Editor
2003-present	Human Gene Therapy, Editor-in-Chief
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HONORS AND AWARDS:

1976	Phi Beta Kappa, Albion College
1977-1980	National Science Foundation Predoctoral Fellowship, University of Michigan
1980-1984	Fellow in the Medical Scientist Training Program, University of Michigan
1982	Thomas Francis, Jr. Memorial Award, March of Dimes
1983	University of Michigan Student Achievement Award
1984	Medical Scientist Training Program Award for Excellence
1984	Dean's Award for Research Excellence
1984	William Dodd Robinson Award for Excellence in Internal Medicine
1989	Young Investigator's Award of the Central Society for Clinical Research
1990	Hickman Lecturer, Central Society for Clinical Research
1991	Jerome W. Conn Award for Distinguished Research by a Junior Faculty Member
1992	Henry Russell Award for Outstanding Faculty Member at University of Michigan
1992	Distinguished Alumni Award, Albion College
1993	Philadelphia Business Journal Health Care Heroes Award
1998	Maurice Hilleman-Merck Research Laboratories Lecturer of the American Society for Virology
1998	Keynote Speaker, Albion College Opening Convocation
2000	Keynote Speaker, Penn State College of Medicine Graduate Student Research Forum
2000	Keynote Speaker, University of Medicine and Dentistry of NJ, Research Day
2001	Keynote Speaker, American Association for Laboratory Animal Science Opening Session

MEMBERSHIPS AND OFFICES IN PROFESSIONAL SOCIETIES:

1990-present	American Association for the Study of Liver Diseases, Member
1990-present	American Association for the Advancement of Science, Member
1990-present	Federation of American Societies for Experimental Biology
1992-present	American Federation for Clinical Research
1992-present	American Society for Clinical Investigation

1993-present	John Morgan Society
1994-present	American Society for Microbiology
1995-present	Molecular Medicine Society
1996-present	American Society of Gene Therapy, Member
1998-1999	American Society of Gene Therapy, President
1999-2004	American Society of Gene Therapy, Advisory Board Member
1998-present	Association for Patient-Oriented Research, Founding Member
2000-present	Regenerative Medicine Society, Member
2001-2004	American Society of Gene Therapy, Gene Therapy of Genetic Diseases Committee, Member

CERTIFICATION AND LICENSURE:

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Ph.D. Thesis: Human Hypoxanthine-Guarnine Phosphoribosyltransference: Molecular Basis of the Enzyme Deficiency States

I. Completed Publications In Peer Reviewed Journals

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2. Anderson JJ, Wilson JM and Oxender DL. Defective transport and other phenotypes of a periplasmic "leaky" mutant of *Escherichia Coli* K-12. J Bacteriol 140:351-358, 1979.

3. Wilson JM, Mitchell BS, Daddona PE and Kelley WN. Purinogenic immunodeficiency diseases: Differential effects of deoxyadenosine and deoxyguanosine on DNA synthesis in human T lymphoblasts. J Clin Invest 64:1475-1484, 1979.

4. Wilson JM, Baugher BW, Landa LE and Kelley WN. Human hypoxanthine-guanine phosphoribosyltransferase: Purification and characterization of mutant forms of the enzyme. J Biol Chem 256:10306-10312, 1981.

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7. Wilson JM, Baugher BW, Mattes PM, Daddona PE and Kelley WN. Human hypoxanthine-guanine phosphoribosyltransferase: Demonstration of structural variants in lymphoblastoid cells derived from patients with a deficiency of the enzyme. J Clin Invest 69:706-715, 1982.

8. Wilson JM, Tarr GE, Mahoney WC and Kelley WN. Human hypoxanthine-guanine phosphoribosyltransferase: Complete amino acid sequence of the erythrocyte enzyme. J Biol Chem 257:10978-10985, 1982.

9. Wilson JM, Landa LE, Kobayashi R and Kelley WN. Human hypoxanthine-guanine phosphoribosyltransferase: Tryptic peptides and posttransitional modification of the erythrocyte enzyme. J Biol Chem 257:14830-14834, 1982.

10. Wilson JM, Tarr GE and Kelley WN. Human hypoxanthine (guanine) phosphoribosyltransferase: An amino acid substitution in a mutant form of the enzyme isolated from a patient with gout. Proc Natl Acad Sci USA 80:870-873, 1983.

11. Wilson JM, Kobayashi R, Fox IH and Kelley WN. Human hypoxanthine-guanine phosphoribosyltransferase: Molecular abnormality in a mutant form of the enzyme ($HPRT_{Toronto}$). J Biol Chem 258:6458-6460, 1983.

12. Argos P, Hanei M, Wilson JM and Kelley WN. A possible nucleotide-binding domain in the tertiary fold of phosphoribosyltransferases. J Biol Chem 258:6450-6457, 1983.

13. Wilson JM and Kelley WN. Molecular basis of hypoxanthine-guanine phosphoribosyltransferase deficiency in a patient with the Lesch-Nyhan syndrome. J Clin Invest 71:1331-1335, 1983.

14. Daddona PE, Mitchell BS, Morenweiser HJ, Davidson BL, Wilson JM and Koller CA. Adenosine deaminase deficiency with normal immune function: An acidic enzyme mutation. J Clin Invest 72:483-492, 1983.

15. Wilson JM, Frossard P, Nussbaum R, Caskey CT and Kelley WM. Human hypoxanthine-guanine phosphoribosyltransferase: Detection of a mutant allele by restriction endonuclease analysis. J Clin Invest 72:767-772, 1983.

16. Wilson JM, Young AB and Kelley WN. Hypoxanthine-guanine phosphoribosyl-transferase deficiency: The molecular basis of the clinical syndromes. New Engl J Med 309:900-910, 1983.

17. O'Toole TE, Wilson JM, Gault MH and Kelley WN. Human adenine phosphoribosyl-transferase: Characterization from subjects with a deficiency of enzyme activity. Biochem Genet 21:1121-1134, 1983.

18. Wilson JM and Kelley WN. Human hypoxanthine-guanine phosphoribosyl- transferase: Structural alteration in a dysfunctional enzyme variant ($HRPT_{Munich}$) isolated from a patient with gout. J Biol Chem 259:27-30, 1984.

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56. Davidson BL, Allen ED, Kozarsky KF, Wilson JM, and Roessler BJ. A Model System for *In vivo* Gene Transfer into the CNS Using an Adenoviral Vector. Nat Genet 3:219-223, 1993.

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73. Yang Y, Nunes FA, Berencsi K, Furth EE, Gönczöl E and Wilson JM. Cellular Immunity to Viral Antigens Limits E1-Deleted Adenoviruses for Gene Therapy. Proc Natl Acad Sci USA 91:4407-4411, 1994.

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75. Grossman M, Raper SE, Kozarsky K, Stein EA, Engelhardt JF, Muller D, Lupien PJ, and Wilson JM. Successful *Ex vivo* Gene Therapy Directed to Liver in a Patient with Familial Hypercholesterolemia. Nat Genet 6:335-341, 1994.

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Customer No. 00270

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of	) Group Art Unit: 1632
James M. Wilson et al	) Examiner: R. Shukla
Appln No. 09/757,673	) Confirmation No. 8771
Filed: January 10, 2001	) Docket No. GNVPN.019B1USA
For: METHOD FOR RECOMBINANT ADENO-ASSOCIATED VIRUS-DIRECTED GENE THERAPY	)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION PURSUANT TO 37 CFR 1.132

Sir:

I, Guangping Gao, residing at 408 Yorkshire Road, Rosemont, Pennsylvania 19010-1119, do declare and state that:

1. I am currently Director of the Vector Program at the Department of Medicine, School of Medicine, University of Pennsylvania. I have been employed in the University of Pennsylvania and have been involved in the vector production for the gene therapy program since 1994. The details of my educational background, including my postgraduate training and fellowship appointments, my appointments, memberships in professional and scientific societies, and my publications are provided in the attached copy of my *curriculum vitae*.

2. I am familiar with the above-identified patent application and have reviewed the current Office Action and pending claims.

3. I have also reviewed US Patent No. 5,858,351, Podsakoff et al ("Podsakoff") and Fisher et al, *J. Virol.*, 79:520-532 (1996). Podsakoff at column 18, lines 20-35, described production of recombinant AAV (rAAV) virions in human 293 cells. 293 cells were transfected by standard calcium phosphate precipitation with rAAV, infected with human adenovirus serotype 2 (Ad2) and incubated as described. Cells were ultimately layered onto a cesium chloride gradient centrifugation, extracted from the gradient and heat inactivated. While heat treatment of the helper adenovirus can affect the infectivity of the adenovirus, heat treatment does not remove helper adenovirus or adenoviral protein contaminants. Helper adenovirus and adenoviral protein contaminants are immunogenic, regardless of heat treatment.

4. The experiment described in this Declaration was performed, in part, by me personally, and, in part, under my direction, in the laboratories of The University of Pennsylvania.

5. The recombinant adeno-associated viruses were produced and purified as described in the specification. More particularly, a total of 1×10^9 293 cells were seeded in 150 mm plates. These 293 cells are a late passage cell seed with a passage number around 110 (about 75 from the original ATCC stock of 35 passages). These cells have been optimized for adenovirus production, as the cells used in the original experiments were not available. The next day, the cells were first infected with an E1-deleted adenovirus helper, H5.010CBALP, at an MOI of 200 viral particles per cells in DMEM medium supplemented with 2% of FBS. At 2 hours post infection, the cells were co-transfected with a pAAV2rep/2cap trans-and a pAAV2CMVLacZ cis-plasmid exactly as described in Fisher *et al*, *J Virol*, 70:520-532 (1996) ("Fisher article"), which is cited and incorporated by reference in the specification on page 15, lines 11-13, and also cited on page 34, lines 6-7 of the specification. Sixteen hours

later, the infection/transfection medium was replaced with fresh DMEM containing 2% FBS. The cells were harvested at 40 hours post infection. For the studies described in Paragraphs 7, 8, 9, and 10 crude lysate was subjected to the purification process as described in the specification and the Fisher article. After each of 4 cesium chloride gradient centrifugations, ¼ AAV containing fraction (equivalent to AAV produced from approximately 2.5-5 x 10^8 cells) was desalted and the remaining AAV-containing fraction was put onto the next run of CsCl gradient centrifugation. At the end, a total of 4 desalted AAV containing fractions were collected.

6. **Level of total adenoviral capsid proteins in a crude rAAV lysate prior to a first round of cesium chloride gradient centrifugation and without heat inactivation.**

Two independent transfections were performed as described in Paragraph 5. Crude lysate from these two transfections was used in this study.

A. SDS-PAGE, blotting and protein detection:

18.78, 7.5, 3.75 and 1.5 µl of crude lysate from two independent transfections were diluted in NuPAGE LDS reducing buffer (4X) (Invitrogen) and heated at 70° for 10 minutes. 6.5x10^8 pts of CsCl purified H5.010CBALP was loaded onto the gel as a reference control. Electrophoresis was carried out in a NuPAGE 4-12% Bis-Tris Gel (Invitrogen) at 200V and 70 mA for 1 hour. See Blue Plus2 Pre-Stained Molecular weight Markers (Invitrogen) were used as standards. After electrophoresis the gels were blotted onto Immun-Blot PVDF membranes in a Mini Trans-blot Transfer cell (Bio-Rad) at 30 V for 12 hours at 4° C. After transfer, the Immun-Blot PVDF membranes were stained with Ponceau Red (Sigma).

B. Western Blot:

The western blot was performed using Western Breeze kit from Invitrogen. PVDF membranes were blocked with Blocking solution for 1 hour on a rotary shaker set at 1 rev/sec. The membranes were washed once with washing buffer 5 minutes and incubated for 1 hour at room temperature with 1:1,000 dilution of

primary antibody diluted in Primary antibody solution. The membranes were washed 5 times for 25 minutes. (5 minute incubations) and incubated for 30 minutes with goat anti rabbit IgG HRP 1:1000 dilution in TBS (PBS+0.05% Tween 20). PVDF membranes were washed 5 times for 25 minutes and immunoreactive bands were revealed with ECL Western Blot kit (Amershan Bioscience). See Fig. 1.

C. Result analysis:

1. Both samples showed adenovirus bands with the same intensity, indicating that adenovirus contaminations in two independent transfection/infection experiments were at the same level.

2. The adenovirus band intensity in 1.5 µl lysate loading lanes was 2-3 time stronger than the reference control. Therefore adenovirus protein contamination in a 25 plate lysate can be estimated as the following: $6.5 \times 10^8 \times 3 \times 1000/1.5 \times 25 = 3.25 \times 10^{12}$ virus particle equivalent.

7. **Alkaline phosphatase transduction assay**

This assay is performed to detect the amount of infectious adenoviral particles, as determined by the expression of reporter gene.

(a) For the assay validation, CsCl gradient purified E1-deleted adenovirus expressing human placenta alkaline phosphatase (H5.010CBALP, 4×10^{12} pts/ml) was used. A vial of the virus (400 µl) was thawed on ice and 100 µl was taken out. Then the samples were serially diluted from 10^{-1} to 10^{-6} and used to infect A549 cells that were seeded in 24 well plates at a density of 5×10^5 cells per well one day prior to the infection. Twenty-four hours after infection, cells were fixed in 0.5% glutaraldehyde/PBS, washed with PBS and incubated at 65 °C for 30 minutes to inactivate the endogenous alkaline phosphatase activity. Under this condition, human placenta alkaline phosphatase expressed from the adenovirus vector remains active because of its heat resistant nature. Cells were then stained with NBT/BCIP at room temperature for 1 hour and purple cells were counted under a light microscope. Average number of purple cells counted in 3 non-infected control wells was taken as the background staining and subtracted from the counts in sample wells.

(b) To detect infectious H5.010CBALP in different AAV fractions from the 1st, 2nd, 3rd and 4th centrifugations, 10 µl samples underwent 10-fold series of dilution and were used to infect 24-well plates of A549 cells for 24 hours. Alkaline phosphatase staining and counting of the infected cells were carried out.

(c) The results of the experiments described herein demonstrate that there is a reduction in infectious adenovirus particles in rAAV preparations achieved with each subsequent round of CsCl gradient centrifugation.

8. **Four-step CsCl gradient centrifugation efficiently removes contaminating helper adenovirus from the AAV preparation**

(a) The data in this Paragraph shows the percent reduction in infectious adenoviral particles following each spin, without heat inactivation of the preparation. This was performed to illustrate the total number of contaminating infectious adenoviral particles.

Table 1
Effectiveness of CsCl gradient centrifugation steps to remove infectious helper adenovirus without heat inactivation

Samples	Titer (TU/ml)	Remaining Transduction activity	De-contamination Efficiency
1st spin	6.8×10^9	100%	0%
2nd spin	3.12×10^9	45.88%	54.12%
3rd spin	1.87×10^8	2.75%	97.25%
4th spin	4.29×10^7	0.63%	99.37%

(b) When AAV fractions from each of 4 centrifugations were assayed for ALP transduction, the data clearly demonstrated that the second centrifugation only removed an additional 50% of helper virus remaining from the first centrifugation, whereas the 3rd and 4th centrifugations further reduced adenovirus contamination to 3% and less than 1% levels, respectively (Table 1). The data

obtained from the first centrifugation was set as the start point to calculate relative decontamination efficiency in further centrifugation steps.

(c) This ALP transduction data indicates efficient removal of contaminating infectious helper adenovirus from the AAV fractions using the techniques described in the specification.

9. **Heat Inactivation Does Not Alter Total Adenovirus Contaminants**

(a) In the present study, the effect of heat inactivation on rAAV prepared as described at various time points is provided.

(b) The data obtained from the first centrifugation was set as the start point to calculate relative decontamination efficiency in further centrifugation steps.

Table 2

Effectiveness of CsCl gradient centrifugation steps to remove infectious helper adenovirus

Sample	Titer (TU/ml)	Remaining Transduction activity	De-contamination Efficiency
Heated for 60 min			
1st spin	1.20×10^0	100%	0%
2nd spin	1.20×10^0	0%	100%
3rd spin	1.1×10^0	0%	100%
4th spin	1.00×10^0	0%	100%

(c) This transduction data indicates efficient removal of contaminating infectious helper adenovirus from the AAV fractions following three and four spins. This data is not relevant to the contamination, because this effectively illustrates only that infectious adenoviral particles are destroyed following 60 minutes of heat inactivation. This assay does not measure total adenoviral contaminants present.

10. **Multiple runs of CsCl gradient centrifugation remove contaminating adenovirus proteins from AAV fractions efficiently.**

(a) Equal amounts of AAV fractions from each centrifugation (20 μL) were subjected to a Western blot assay using rabbit polyclonal antibody to either adenovirus (genome copies, GC) or purified adenoviral hexon protein to detect adenovirus protein remaining in the AAV fractions, in order to determine the efficiency of each centrifugation step in purifying AAV vector from contaminating adenovirus proteins.

(b) The Western blot was performed using Western Breeze™ kit from Invitrogen. PVDF membranes were blocked with blocking solution for 1 hour on a rotary shaker set at 1 rev/sec. The membranes were washed once with washing buffer for 5 minutes and incubated for 1 hour at room temperature with 1:1,000 dilution of primary antibody diluted in primary antibody solution. The blots were then washed 5 times for 5 minutes each and then incubated for 30 minutes with 1:1000 dilution of goat anti rabbit IgG HRP in TBS (PBS+0.05% Tween 20). PVDF membranes were washed 5 times for a total of 25 minutes and immunoreactive bands were revealed with ECL Western Blot kit (Amersham Bioscience). For the positive control, 6.5×10^8 particles of CsCl gradient centrifugation purified adenovirus vector were used in the analysis.

(c) Fig.2A shows the results of Ponceau Red staining for total protein contents; Fig. 2B shows the results of Western blot using rabbit polyclonal antibody against adenovirus, and Fig. 2C shows the results of Western blot using rabbit polyclonal antibody against adenovirus hexon protein, as compared to 1 or 2 spins. The estimated number of total adenoviral particles (both infectious and non-infectious) following each round of centrifugation is provided in the following table.

Table 3

Effectiveness of CsCl gradient centrifugation steps to remove total contaminating adenovirus proteins (adenoviral (Ad) particle equivalents)

Samples	Contaminating Ad Proteins (Ad Particle Equivalents)
1st spin	3.4×10^{12}
2nd spin	2.55×10^{12}
3rd spin	1.7×10^{12}
4th spin	8.5×10^{11}

These values are estimated based on the Western Blot of Fig. 2B, showing total hexon, capsid and fiber proteins, which are the major proteins of the adenoviral capsid.

(d) These results demonstrate that at least four rounds of cesium chloride gradient centrifugation provide a much greater reduction in adenovirus protein contaminants than one or two spins.

11. The data presented herein establish that the prior art does not provide rAAV with the great reduction in helper adenovirus and adenovirus protein contamination taught by the present invention. These data further establish that adenovirus contamination in rAAV preparations is at the same level in independent rAAV productions.

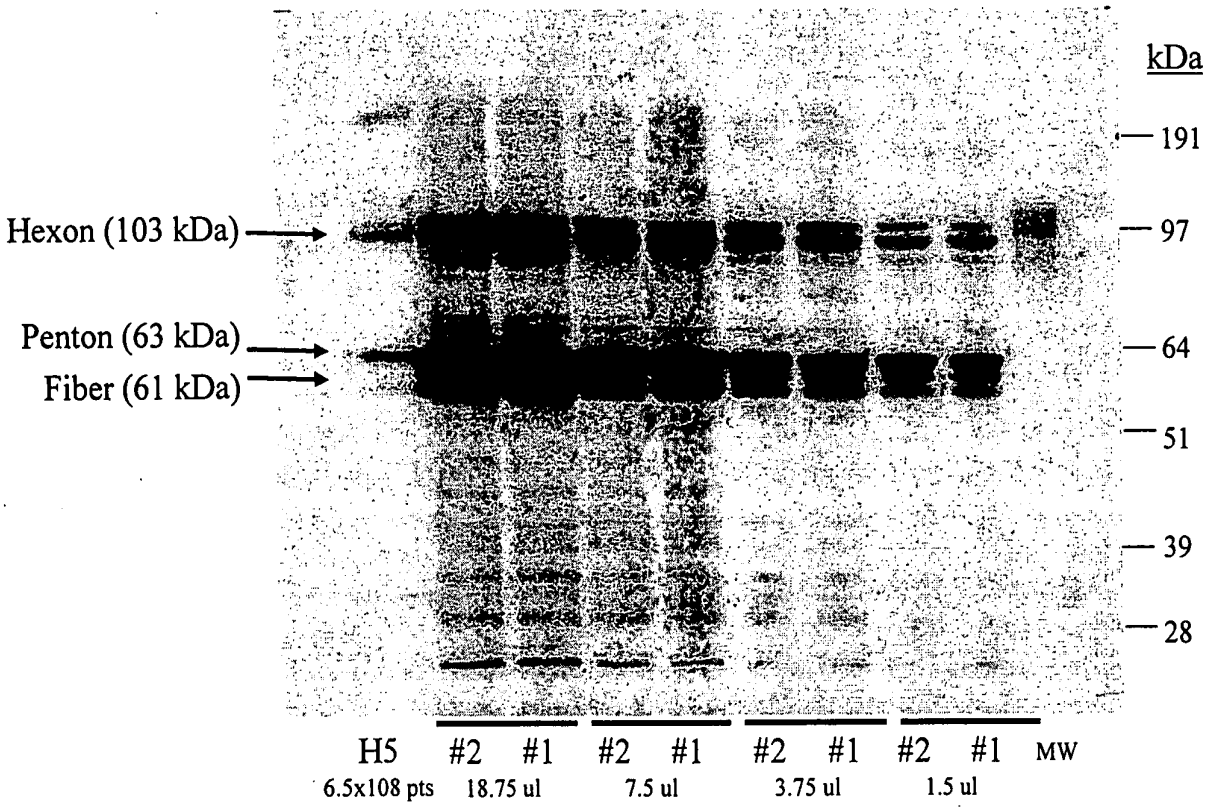
12. It is well established in the art that heat treatment of adenovirus preparations can affect the infectivity of adenovirus. This is further supported by the data presented in Table 2. Heat treatment does not remove helper adenovirus or adenoviral protein contaminants, as is illustrated in Table 3 (showing the reduction of total adenoviral contaminants according to the present invention). Helper adenovirus and adenoviral protein contaminants are immunogenic, regardless of whether the preparation has been heat treated or not heat treated.

13. As a person signing below, I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issues thereon.

Guangping Gao

Date: 5/11/04

Fig. 1 Western Blot. Polyclonal Ab (Anti-H5)



Protein Stain
(Ponceau Red)

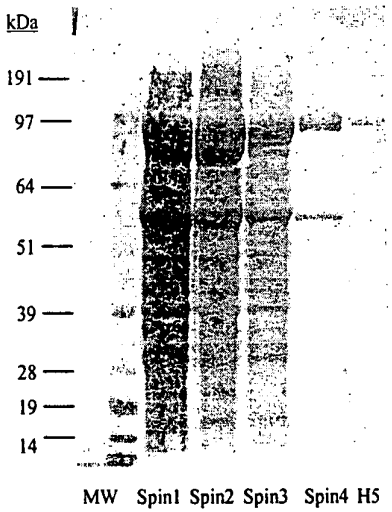


Fig. 2A

Western Blot

Polyclonal Ab (Anti-H5)

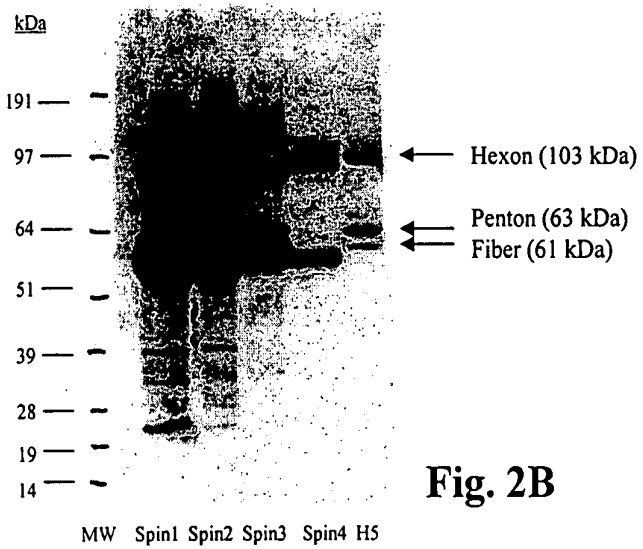


Fig. 2B

Western Blot

Polyclonal Ab (Anti-Hexon)

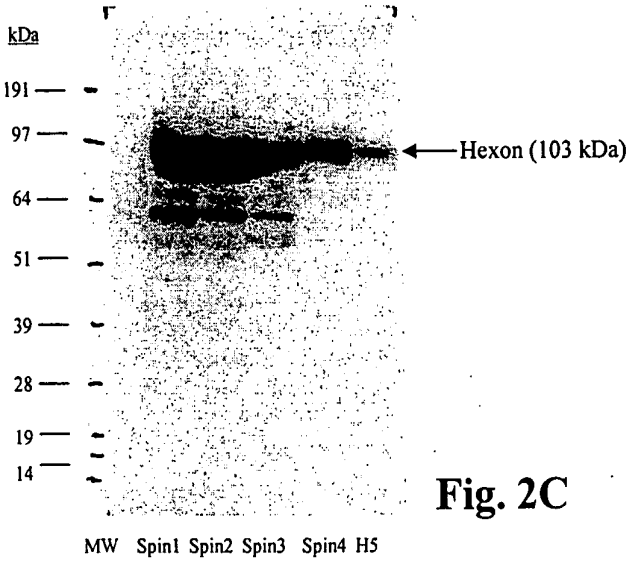


Fig. 2C

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1978-82	Bachelor's Degree of Medicine West China University of Medical Sciences
1988-90	M.S. Florida International University
1990-94	Ph.D. Florida International University (Biological Sciences)

Postgraduate Training and Fellowship Appointments:

1988-89	Fellowship, Biomedical Engineering, World Health Organization/Florida International University, Miami
1994-96	Postdoctoral Fellow, Gene Therapy, Dr. James Wilson's Laboratory Institute for Human Gene Therapy University of Pennsylvania, Philadelphia

Faculty /Staff Appointment:

1986-1988	Instructor in Biochemistry, Department of Biochemistry, College of Pharmaceutical Sciences, West China University of Medical Sciences, Chengdu, P.R. China
1996-1998	Assistant Director Human Applications Laboratory Institute for Human Gene Therapy University of Pennsylvania Philadelphia, U.S.A.
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